

K132629

SECTION 5: 510(k) SUMMARY**Submitter:**

Stryker Sustainability Solutions
1810 W Drake Drive
Tempe, Arizona 85283

Contact:

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Date of preparation: August 20, 2013

Name of device: *Trade/Proprietary Name:* Reprocessed Trocars and Stability Sleeve

Classification Name: Laparoscope, General & Plastic Surgery, Reprocessed

Classification Information:

Class:	II
Panel:	Gastroenterology/Urology
Product Code:	NLM
Citation:	21 CFR §876.1500

Predicate Device	510(k) Title	Manufacturer
K062497	Reprocessed Trocars	Stryker Sustainability Solutions
K070059	Reprocessed Xcel Bladed Trocars	Stryker Sustainability Solutions
K122511	ENDOPATH XCEL BLADELESS TROCAR WITH OPTIVIEW TECHNOLOGY ENDOPATH XCEL BLUNT TIP TROCAR WITH OPTIVIEW TECHNOLOGY	Ethicon Endo-Surgery

Device Description:**Reprocessed Bladeless Trocar:**

The Reprocessed Bladeless Trocar, is a sterile single patient use instrument consisting of a radiolucent sleeve (cannula) and obturator. The obturator contains a clear, tapered optical element. The 5 mm obturator accommodates an appropriately sized 0° endoscope and provides visibility of individual tissue layers during insertion. The trocar sleeve contains two seals that accommodate instruments 5 mm in diameter. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

Reprocessed Dilating Tip (Bladed) Trocar:

The Reprocessed Dilating Tip Trocar is a sterile, single patient use instrument consisting of a radiolucent sleeve (cannula) and obturator. The obturator has a sharp, flat-bladed tip and spring-loaded shield. The shield is designed to cover the flat-bladed tip to protect internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered. The trocar sleeve contains two seals that accommodate instruments 5 mm in diameter. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

Reprocessed Stability (Universal) Sleeve (Cannula):

The Reprocessed Stability Sleeve is a sterile, single patient use device with a radiolucent sleeve. The trocar sleeve contains two seals that accommodate instruments 5 mm in diameter. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

Indications for Use:**Reprocessed Bladeless Trocar:**

The Reprocessed Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

Reprocessed Dilating Tip Trocar:

The Reprocessed Dilating Tip Trocar has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

Reprocessed Stability Sleeve:

The Reprocessed Stability Sleeve has application in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

Technological Characteristics:

The design, materials, and intended use of Reprocessed Bladeless Trocar, Reprocessed Dilating Tip Trocar, and Reprocessed Stability Sleeves are identical to the predicate devices. The mechanism of action of Reprocessed Bladeless Trocar, Reprocessed Dilating Tip Trocar, and Reprocessed Stability Sleeves are identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of Bladeless Trocars, Dilating Tip Trocars, and Stability Sleeves includes removal of adherent visible soil and decontamination. Each individual Bladeless Trocar, Dilating Tip Trocar and Stability Sleeve is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Bladeless Trocar, Reprocessed Dilating Tip Trocar, and Reprocessed Stability Sleeves. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Bladeless Trocar, Reprocessed Dilating Tip Trocar, and Reprocessed Stability Sleeves perform as originally intended.

Conclusion:

Stryker Sustainability Solutions concludes that the reprocessed devices are as safe and effective to the predicate devices as described herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 31, 2013

Stryker Sustainability Solutions
% Ms. Amanda Babcock
Regulatory Affairs Lead
1810 West Drake Drive
Tempe, Arizona 85283

Re: K132629

Trade/Device Name: Reprocessed Dilating Tip Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NLM
Dated: September 9, 2013
Received: September 23, 2013

Dear Ms. Babcock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (If known): K132629

Device Name: Reprocessed ENDOPATH® XCEL™ Bladeless Trocar with OPTIVIEW® Technology

Indications For Use: The Reprocessed Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

Device Name: Reprocessed ENDOPATH® XCEL™ Dilating Tip Trocar with OPTIVIEW® Technology

Indications For Use: The Reprocessed Dilating Tip Trocar has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

Device Name: Reprocessed ENDOPATH® XCEL™ Universal Trocar Stability Sleeve

Indications For Use: The Reprocessed Stability Sleeve has application in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132629

Stryker Sustainability Solutions
Reprocessed Trocars and Stability Sleeve
Traditional 510(k)

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